DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
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October 24, 2003

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 04-06

Theodore J. Svendsen, President
Svendsen Brother's Fish Company, Inc.
6247 5th Avenue Northwest
Seattle, Washington 98107-2122

WARNING LETTER

Dear Mr. Svendsen:

On July 18, 21, and 24, 2003, we inspected your seafood processing facility, located at 745 South Myrtle Street, Seattle, Washington. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Point (HACCP) regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HAACP plan that complies with this section, or to otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your refrigerated, vacuum packaged, salt-cured, ready-to-eat salmon products are adulterated in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or whereby they may have been rendered injurious to health. You can find the Act, the Seafood HACCP regulations, and the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001 (the Hazard Guide), through links in FDA's homepage at www.fda.gov.

The deviations are as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards and have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (c)(1). A food safety hazard is defined in 21 CFR 123.3(f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." Your firm's HACCP plan for mild salt cured salmon does not list the food safety hazards of Clostridium botulinum growth and toxin formation in your vacuum packaged raw material, nor does it list the food safety hazard of parasites.

a) Your firm receives raw refrigerated vacuum-packaged salmon "chubs" and stores them for further processing into salt cured salmon products. Strict temperature control at or below 38°F is the sole barrier to Clostridium botulinum growth and toxin formation in fresh, raw, refrigerated, reduced oxygen-sealed (i.e., vacuum or modified atmospheric packaged) fish. You have not identified Clostridium botulinum as a food safety hazard associated with your vacuum packaged raw material, and your HACCP plan does not include critical limits at receiving and during raw material storage to monitor and control temperatures at or below 38°F to control this hazard. A critical limit is defined in 21 CFR 123.3(c) as a "maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard."

b) Your firm's HACCP plan for mild "salt" cured salmon does not list the food safety hazard of parasites. The salmon used in this product is fresh (not previously frozen), wild-caught and distributed refrigerated to be consumed without heating or cooking.

2. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the critical control points, to comply with 21 CFR 123.6(a) and (c)(2). A critical control point is defined in 21 CFR 123.3(b) as a "point, step, or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels."

   Your firm's HACCP plan for mild "salt" cured salmon does not list the critical control point of "curing" for controlling the food safety hazard of pathogen growth and potential toxin formation. Discussions during the inspection revealed that you initially cure the product, [redacted]. This process time is described as occurring from [redacted] to [redacted] days in [redacted].

   Our investigator collected records of your Cure Room Temperature Log that show temperatures as high as 49°F. Holding food products for extended times at elevated temperatures (i.e., in excess of 40° F) will likely result in the growth of pathogenic microorganisms and potential toxin formation. Consequently, your HACCP plan needs to address this curing process as a critical control point to control this potential food safety hazard. FDA recommends that you perform continuous temperature monitoring in order to ensure that the temperature remains at or below 40° F for the duration of this process.

3. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3).

   a) Your firm's HACCP plan for mild "salt" cured salmon lists critical limits that are not adequate to control pathogen growth and potential toxin formation at the "cooler" critical control point. Your critical limit lists "cooler(s) not to exceed [redacted] deg F

temperature for more than [redacted] days" at the coolers critical control point. There appear to be several cooler storage steps that occur during the handling of your salmon products, including refrigerated raw material storage, in-process storage for [redacted] days, and finished product storage. Continuous temperature control during all refrigerated storage steps is necessary to control pathogen growth and potential toxin formation and your plan should address all storage steps. In addition, the temperature listed in the plan is not adequate to control growth and potential toxin formation from pathogenic microorganisms. The Hazard Guide recommends 40°F as the appropriate temperature for refrigerated storage conditions in order to reduce the likelihood for growth of pathogenic microorganisms and toxin formation. One exception, as mentioned previously in this letter, involves the refrigerated storage of vacuum or modified atmospheric packaged raw fish where there is no secondary barrier to Clostridium botulinum growth and toxin formation. The Hazard Guide recommends control of the temperature at or below 38°F for these types of products.

b) Your firm's HACCP plan for mild "salt" cured salmon does not list adequate critical limits at the "salting" critical control point to control pathogen growth and potential toxin formation. Your critical limits list "ratio of salt to fish will be minimum of [redacted]% [representing water phase salt, as indicated during discussions] or [redacted]# salt to [redacted]# of fish or [redacted]# salt to [redacted]# of fish." The plan indicates that it is associated with "Mild cured Salmon." However, you process several products (i.e., salt cured salmon cubes made from minced salmon, salt cured salmon cubes made from boned and skinned fillets, hard-salted salmon fillets, and mild cured salmon fillets) in various sized buckets and/or plastic totes. There is no indication that this plan is applicable to all of your salt cured salmon products and no evidence demonstrating that the salting processes, as listed, will adequately achieve the target water phase salt level for each product. Moreover, there are no critical limits reflecting the processing parameters necessary for achieving the final water phase salt of [redacted]% that is listed in the plan. For example, there is no process time listed, there is no indication that fish fillet or minced cube size or any uniformity in size is critical for achieving the final water phase salt levels, etc. Additionally, the HACCP plan should indicate that the value of [redacted]% listed in the plan represents water phase salt. Please also be advised that because implementation of the control strategies for your various products may differ from one product to another, you may want to consider separate HACCP plans for each product.

4. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor sanitation conditions and practices during processing with sufficient frequency to ensure conformity with 21 CFR Part 110, as evidenced by our investigator observing that four out of five workers did not wash their hands before handling raw, ready-to-eat products; and several instances of employees touching insanitary surfaces and then touching raw, ready-to-eat products without first washing their hands.

In addition, we reviewed the labels for the "[redacted] Cubed Salt Salmon" and the "[redacted] Salted Chum Salmon" that the FDA investigator collected during the inspection of your firm. Our review reveals that these labels cause the products to be misbranded within the meaning of section 403(q)(1) of the Act in that the labels fail to bear nutrition labeling as required by 21 CFR 101.9, and the products are not exempt from this requirement under section 403(q)(5) of the Act.

For additional information on control strategies associated with Clostridium botulinum growth and toxin formation, please refer to Chapter 13 of the Hazard Guide. For additional information on control of parasites, please see Chapter 5 of the Hazard Guide, and for additional information on control of pathogen growth (other than Clostridium botulinum) please refer to Chapter 12 of the Hazard Guide.

We may take further action if you do not promptly correct these violations. For instance, we may take action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Current Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa M. Althar at (425) 483-4940.

Sincerely,

Charles M. Breen
District Director

cc: WSDA with disclosure statement